

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/595,760 | 06/16/00 | REDDY | E 6056-0272 |

HM22/0119

EXAMINER

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POWERS, F

ART UNIT PAPER NUMBER

1626

DATE MAILED:

01/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | | |
|------------------------------|-----------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/595,760 | REDDY ET AL. |
| | Examiner Fiona T. Powers | Art Unit 1626 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 October 2000.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 15 and 16 is/are allowed.
- 6) Claim(s) 1-11,17-19,22 and 25 is/are rejected.
- 7) Claim(s) 12-14,20,21,23, 24 and 26 is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 18) Interview Summary (PTO-413) Paper No(s). _____
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: _____

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Receipt is acknowledged of the information disclosure statement filed October 13, 2000, which has been entered in the file.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 3, it appears that "benzothzaolyl" should be -benzothiazolyl-.

Claim 4 is dependent on itself. The dependency should be changed to claim 3.

Claim 25 refers to the reactant compound of formula II according to claim 22. However, the reactant compound in claim 22 is of the formula IV.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1, 5, 17 to 19, 22 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Cuberes-Altisent et al. (WO 99/62884), cited by applicants.

The reference discloses the claimed compounds and pharmaceutical compositions wherein X is trifluoromethyl or methyl and Z is substituted phenyl. Note Examples 1, 3, 5, 8, 11, 13-16, 18, 20-24, 26, 28, 30, 44 to 49, 51 to 58, 60 to 64, 75 and 76. The reference also discloses the claimed method for preparing the compounds of the formula I by reacting a compound of the formula IV with a 4-sulfamyl phenyl hydrazine. Note Method A on pages 7 to 8.

Claims 1 and 6 to 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Faidallah et al. (Pak. J. Ind. Res., 35(1-2), 8-13, 1992), cited by applicants. *See J. 27*

The reference discloses the claimed compounds of the formula I wherein X is of the formula II and Z is substituted phenyl. Note Compound Nos. 3a, 3b, 3c and 3d of the scheme on page 12.

Claims 1 to 3, 5 to 8 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Makki et al. (Chem. Abstr., 121:134017, 1994).

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The reference discloses the claimed compound wherein X is substituted or unsubstituted phenyl and Z is unsubstituted thienyl. Note the abstract.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5, 17 to 19, 22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cuberes-Altisent et al. (WO 99/62884).

The reference discloses the claimed compounds and pharmaceutical compositions wherein X is trifluoromethyl or methyl and Z is substituted phenyl. Note Examples 1, 3, 5, 8, 11, 13-16, 18, 20-24, 26, 28, 30, 44 to 49, 51 to 58, 60 to 64, 75 and 76. The compounds of the reference are useful for the treatment of inflammation and other processes mediated by cyclooxygenase-2. The reference also discloses the claimed method for preparing the compounds of the formula I by reacting a compound of the formula IV with a 4-sulfamyl phenyl hydrazine. Note Method A on pages 7 to 8.

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The claimed compounds which are position isomers, homologs or close structural analogs of the compounds disclosed by the reference would have been rendered obvious. One of ordinary skill in the art would have been motivated to make the claimed compounds with the expectation that additional compounds useful for the treatment of inflammation and processes mediated by cyclooxygenase-2 would be obtained. The claimed compounds and pharmaceutical compositions would have been rendered obvious by the teachings of the reference in the absence of any unobvious property. The claimed process for preparing the compounds would have been rendered obvious in the absence of any unobvious result.

Claims 12 to 14, 20, 21, 23, 24 and 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 15 and 16 are allowed.

The references made of record and not relied upon show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fiona T. Powers whose telephone number is 703-308-4535.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Fiona T. Powers
Fiona T. Powers
Primary Examiner
Art Unit 1626

ftp
January 18, 2001